

PATENT
Appeal Brief dated 9/8/05
08/921,533
2880/158

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Törmälä et al.
Serial No.: 08/921,533
Filing Date: September 2, 1997
For: BIOACTIVE AND BIODEGRADABLE COMPOSITES OF
POLYMERS AND CERAMICS OR GLASSES AND METHOD TO
MANUFACTURE SUCH COMPOSITES
Examiner: Lakshmi S. Channavajjala
Art Unit: 1615

NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief-Patents

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450
SIR:

In response to the Notification of Non-Compliant Appeal Brief, Applicants hereby petition for a one-month extension of time, extending the period of response up to and including January 17, 2006. The Office is authorized to charge any fees due or credit any overpayments to Deposit Account 11-0600. Applicants submit the revised Appeal Brief with the subheading for "Status of Amendments," "Evidence Appendix," and "Related Proceedings Appendix."

Respectfully submitted,
KENYON & KENYON

Date: 1/17/06

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APPEAL BRIEF UNDER 37 C.F.R. 41.37

SIR:

This brief is in furtherance of the Notice of Appeal filed on June 8, 2005. Appellants petition for a one-month extension of time extending the period of response in which to file an Appeal Brief up to and including September 8, 2005. The Office is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the appeal brief fee and for this extension of time.

I. REAL PARTY IN INTEREST

Linvatec Biomaterials Oy is the real party in interest for all issues related to this appeal by virtue of the assignment from the inventors to Bionx Implants Oy recorded on February 23, 1998 at Reel 9007 and Frame 0360 and by virtue of the name change filed herewith recording the name change of Bionx Implants Oy to Linvatec Biomaterials Oy.

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02 FC:2251 60.00 DA

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellants, appellant's legal representative, or assignee which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-6 and 9-22 are pending in the present application. Claims 7 was cancelled by the amendment of August 23, 2003 and claim 8 was cancelled by the amendment of April 5, 2005. Claims 1-6 and 9-22 stand finally rejected and are the subject of this appeal. The attached claims reflect the status of the claims as of the Final Office Action of March 8, 2005.

IV. STATUS OF AMENDMENTS

No amendments were made in the Response under 37 C.F.R. 1.116 of April 5, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a biodegradable and bioactive composite material comprising two different reinforcing phases and one matrix phase. One reinforcing phase is a resorbable polymeric reinforcing component and the other reinforcing phase is a ceramic reinforcing component mixed with the matrix component (phase) See page 5, lines 17-19 and Figure 1.

The resorbable polymeric reinforcing component can be a fibrillated biodegradable or bioerodible polymer and the diameter of the reinforcing fibers can vary from between 4 microns and 800 microns, and preferably between 20 microns and 500 microns. The polymeric reinforcing component can be used as plain fiber or in modified form such as braided or woven into two or three dimensional structures. See page 7, lines 10-11. Table 1 provides a list of resorbable polymers that can be used for the resorbable polymeric reinforcing component. See page 14-15.

The ceramic reinforcing component can comprise of bioceramic or bioglass, or a mixture of these and acts as a bioactive, bony ongrowth agent that provides a reservoir of calcium and phosphate ions, thus accelerating the healing time for bony fractures. While

the matrix polymer degrades, bone can attach to the residual ceramic or glass particles. See page 6, lines 9-11. The ceramic reinforcing component has a particle size of between 60 microns and 150 microns. See page 6, line 7. As described by the specification:

The defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles[,] there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

Page 6, lines 14-22.

This biocompatibility is also reported in Example 11 where two sets of sample plates of a composite material with a polymeric matrix component, a resorbable polymeric reinforcing component and a bioglass or bioceramic component (hydroxyapatite) were compared. The mean particle diameter of hydroxyapatite powder in the first set of plates was 7.43 microns and in the second set of plates was 80 ± 20 microns. (See page 13, lines 9-16). Histology studies of ten animals showed that in and around the composite plates from the first set, there existed significantly more giant cells than in the tissue of animals implanted with the composite plates from the second set. See page 13, lines 18-22. Thus, the hydroxyapatite particles of 80 ± 20 microns were shown to be more biocompatible. See page 13, lines 22-23.

The amount of the ceramic reinforcing component can be 0.15 to 0.9 volume fraction and preferably between 0.2 and 0.6 volume fraction. Table 2 provides a list of bioceramics and bioglasses that can be used for the ceramic reinforcing component. See page 15 to 16. The bioceramics or bioglasses can be in the form of a powder, flake, sphere, fiber, or other forms. See page 6, line 6.

The composite material can contain various additives and modifiers which improve the processability of the composite. See page 6, lines 23-24. Such additives include surface modifiers to improve the attachment between the polymeric and ceramic components. See page 6, line 23 to page 7, line 1. The composite can also contain pharmaceutically active agents such as antibiotics, chemotherapeutic agents, wound-healing agents, growth hormones, and anti-coagulants. Such agents are used to enhance the bioactive features of the composite and improve the healing process of the tissue. See page 7, lines 2-5.

The composite materials of the present invention have improved mechanical properties compared to non-reinforced devices because the reinforcement changes the behavior of the material from brittle to ductile and makes the device more reliable under load. See page 4, lines 20-23.

The present invention also provides a method of manufacturing a composite material as described above. The polymer matrix component and the ceramic reinforcing component can be mixed together by powder mixing, melt mixing, or solvent mixing. See page 7, lines 7-9. The mixture of the polymeric matrix component and the ceramic reinforcing component can be combined with the polymeric reinforcing component by melt mixing, by coating, or by using solvent as an intermediate to preform the material. See page 7, lines 11-13. The material can be produced in its final form by various techniques including compression molding, filament winding, mechanical machining, or injection molding to any desired shape. See page 7, lines 14-16.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Office Action of March 8, 2005 finally rejected claims 1-6 and 9-22 as being rendered obvious under the judicially created doctrine of obviousness-type double patenting by claims 1-10 of U.S. Patent No. 6,406,498 to Tormala ("the '498 patent").

VII. ARGUMENT

Claim 1

Claim 1 recites a bioceramic or bioglass reinforcing component having "a particle size of between 60 μm and 150 μm ." Claims 1-10 of the '498 patent recite glass or ceramic particles dispersed in a polymer matrix but do not recite any size of the particles, let alone a size between 60 microns and 150 microns. As such, Appellants submit that a *prima facie* case of obviousness has not been established.

In the Final Office of March 8, 2005, the Examiner states that "the patented claims are generic to the particle size and optimizing the amount and particle size of bioglass so as to achieve the composite having the desired effect upon administering at the site. . . would have been within the scope of a skilled artisan." Page 2 of Office Action. The '498 patent claims are not generic as to particle size but rather are completely silent as to particle size and therefore, contrary to the Examiner's assertion,

there is no particle size range to optimize based on the '498 patent's claims. The '498 claims simply provide no guidance to any particular particle size range for the claimed bioabsorbable or bioactive particles.

In the Advisory Action of April 22, 2005, the Examiner states that particle size is "defined" in the '498 patent as being between 2 and 200 microns. However, the '498 patent specification only states that "it is also within the scope of the invention to employ glass in the form of fibers (preferably as short fibers, *e.g.* fibers having a diameter of from about 2 to 200 microns)." Col. 5, lines 11-14. Therefore, if anything, glass particle size of between 2 and 200 microns is only described as a preferred embodiment and not a strict definition that must be read into claims 1-10. As such, Appellants submit that this disclosure in the specification of particle size cannot be used as prior art to establish any motivation or guidance to employ bioceramic or bioglass particles having a particle size between 60 microns and 150 microns. Specifically, when considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim, the disclosure of the patent may not be used as prior art. See *In re Boylan* 392 F.2d 1017 (CCPA 1968).

Moreover, as Appellants stated in their Response of April 5, 2005, the Examiner has pointed to no teaching that indicates that particle size of the bioglass or bioceramic reinforcing component is a result-effective variable. A parameter must first be recognized as a result-effective variable, *i.e.* any variable which achieves a recognized result, before the determination of the optimum or workable range might be characterized as routine experimentation. See *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977). The Examiner has pointed to no teaching that indicates that modulating the particle size of a bioglass or bioceramic component in a polymer matrix has an effect on biocompatibility (or achieves any other recognized result). As stated above, all the Examiner has done is state that particle size is "defined" in the '498 patent as being between 2 and 200 microns. As stated above, Appellants submit that this disclosure in the specification of particle size cannot be used as prior art to establish that particle size is a result effective variable.

Furthermore, as Appellants have stated before, the range of particle size recited in claim 1 is critical. Specifically, as Applicant pointed out in the October 25, 2004 Response to Office Action, the August 25, 2003 Response to Office Action and the June

28, 2004 Response to Office Action, this claimed range achieves unexpected results relative to the prior art. The specification states at page 6, lines 14-22:

[t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

The increased biocompatibility seen with coarser particles is supported by Example 11 of the present specification which compares histological studies of composite plates in ten animals with finer hydroxyapatite powder (7.43 microns) and coarser hydroxyapatite particles (80 +/- 20 microns). As shown in Example 11:

in histological studies it was clearly seen, that in and around the composite plates with finer hydroxyapatite powder [7.43 microns] there existed significantly more giant cells than in the tissue of reference animals containing composite plates with coarser hydroxyapatite particles [80 +/- 20 microns]. Thus, coarser hydroxyapatite particles were shown to be more biocompatible.

Page 13, lines 18-23.

Appellants have therefore shown that the claimed particle size of 60 μm to 150 μm of the bioglass or bioceramic reinforcing component is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue compared to particle sizes taught in the art. Specifically, Example 11 describes hydroxyapatite particles between 60 microns and 100 microns (i.e. 80 +/- 20 microns) compared to hydroxyapatite particles within the range used in the prior art (i.e. hydroxybutyrate powder compounded with particular hydroxyapatite powder with a mean particle size of 8.6 microns as described Doyle et al, "In vitro and in vivo evaluation of polyhydroxybutyrate and of polyhydroxybutyrate reinforced with hydroxyapatite," Biomaterials, vol. 12 (November 1991) at page 842).

In response to Appellants' arguments, the Examiner stated in the Advisory Action of April 22, 2005 that "the instant results are pertinent to only hydroxyapatite particles."

In response, Appellants' submit that the unexpected results in the present specification are not in relation to the type of bioglass or bioceramic particle used, but in relation to the range of particle size. Therefore, the fact that Example 11 describes experiments using only hydroxyapatite does not undercut the results that indicate that bioceramic or bioglass particles having a particle size between 60 and 150 microns are more biocompatible than particles used in conventional practice as described in the prior art. For at least this reason, Appellants submit that claim 1 is not rendered obvious by the '498 patent claims.

Claim 2, 17, 18, 19, and 20

Claims 2, 17, 19, and 20 recite a method of manufacturing a biodegradable composite according to claim 1. Claims 1-10 of the '498 patent in no way describe a method of making a biodegradable composite, let alone the specific method as recited by claims 2, 17, 18, 19, and 20. The Examiner has provided no basis for which claims 2, 17, 18, and 20 are rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 2, 17, 18, 19 and 20 are not rendered obvious by claims 1-10 of the '498 patent.

Claim 3

Claim 3 recites that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claim 3, by virtue of its dependency to claim 1), let alone a composite where the polymeric reinforcing component has a fiber diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. The Examiner has provided no basis for which claim 3 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 3 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 4

Claim 4 recites that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component and wherein at least one fiber has variable thickness. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claim 4, by virtue of its dependency to claim 1), let alone a composite where the polymeric reinforcing component has a fiber diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component and wherein at least one of the fibers has a variable thickness. The Examiner has provided no basis for which claim 4 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 4 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 5

Claim 5 recites that the resorbable polymeric reinforcing component is selected from the group consisting of a fabric, a plain polymeric fiber structure, a woven structure and a braided structure. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in any of these forms and a bioceramic or bioglass reinforcing component (as recited by claim 5, by virtue of its dependency to claim 1). The Examiner has provided no basis for which claim 5 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 5 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 6

Claim 6 recites that the form of the bioceramic or bioglass reinforcing component is selected from the group consisting of powder, flakes, spheres and fibers. Claims 1-10 of the '498 patent in no way describe a specific form of the bioactive glass or ceramic particles, let alone the forms recited by claim 6. The Examiner has provided no basis for which claim 6 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 6 is not rendered obvious by claims 1-10 of the '498 patent.

Claims 9 and 10

Claims 9 and 10 recite that the amount of the bioceramic or bioglass reinforcing component is 0.15 to 0.9 and 0.2 to 0.6 volume fraction, respectively. Claims 1-10 of the '498 patent do not recite either of these amounts. In the Final Office of March 8, 2005, the Examiner states that "optimizing the amount and particle size of bioglass so as to achieve the composite having the desired effect upon administering at the site. . . would have been within the scope of a skilled artisan." (See page 2). The '498 patent claims are not generic as to amount of bioglass or bioceramic particles but rather are completely silent as to any amount and therefore, contrary to the Examiner's assertion, there is no amount range to optimize based on the '498 patent's claims. The '498 claims simply provide no guidance to any particular amount range for the claimed bioabsorbable or bioactive particles. Moreover, the Examiner has pointed to no teaching that indicates that the amount of the bioglass or bioceramic reinforcing component is a result-effective variable. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 9-10 are not rendered obvious by claims 1-10 of the '498 patent.

Claims 11 and 12

Claim 11 recites that the composite further comprises additives selected from a specific group including a pharmaceutically active agent and claim 12 recites that the pharmaceutically active agent is selected from a specific group. Claims 1-10 of the '498 patent in no way describe the composite material further comprising additives, let alone the specific additives recited by claims 11 and 12. The Examiner has provided no basis for which claims 11 and 12 are rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 11 and 12 are not rendered obvious by claims 1-10 of the '498 patent.

Claim 13

Claim 13 recites that the resorbable polymeric matrix component is selected from a specific group. Claims 1-10 of the '498 patent in no way describe any specific polymers that can comprise the polymer matrix, let alone the specific polymers recited by claim 13. The Examiner has provided no basis for which claim 13 is rendered obvious by

claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 13 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 14

Claim 14 recites that the bioceramic or bioglass reinforcing component is selected from a specific group. Claims 1-10 of the '498 patent in no way describe any specific types of bioactive glass or ceramic particles, let alone the specific types of particles recited by claim 14. The Examiner has provided no basis for which claim 14 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 14 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 15

Claim 15 recites that the composite material exhibits ductile behavior under load. Claims 1-10 of the '498 patent in no way describe this limitation and the Examiner has provided no basis for which claim 14 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 15 is not rendered obvious by claims 1-10 of the '498 patent.

Claim 16

Claim 16 recites a composite material comprising a bioceramic or bioglass reinforcing component and a resorbable polymeric reinforcing component in fiber form having a diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component, let alone a composite where the polymeric reinforcing component has a diameter greater than the diameter or particle size of the bioceramic or bioglass reinforcing component. The Examiner has provided no basis for which claim 16 is rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claim 16 is not rendered obvious by claims 1-10 of the '498 patent.

Claims 21 and 22

Claims 21 and 22 recite that the resorbable polymeric reinforcing component is in fiber form with a fiber diameter between 4 and 800 microns and 200 and 500 microns, respectively. None of claims 1-10 of the '498 patent teach a composite comprising both a resorbable polymeric reinforcing component in fiber form and a bioceramic or bioglass reinforcing component (as recited by claim 3, by virtue of its dependency to claim 1) or any particular fiber diameter, let alone the specific fiber diameter recited by claims 21 and 22. The Examiner has provided no basis for which claims 21 and 22 are rendered obvious by claims 1-10 of the '498 patent. For at least this reason and the reasons stated above with respect to claim 1, Appellants submit that claims 21 and 22 are not rendered obvious by claims 1-10 of the '498 patent.

APPENDICES

VIII. CLAIMS APPENDIX

The claims in their current form are presented below:

Claim 1. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component and iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component, wherein the bioceramic or bioglass reinforcing component has a particle size of is between 60 μm and $150\mu\text{m}$.

Claim 2. A method of manufacturing a biodegradable composite according to claim 1, comprising the steps of:

- a) selecting at least one first polymer for the matrix;
- b) selecting at least one bioceramic material, bioglass material or mixture thereof for use as the bioceramic or bioglass reinforcing component;
- c) mixing said first polymer and said bioceramic or bioglass reinforcing component together to form a mixture;
- d) selecting at least one second polymer in a fiber form for the resorbable polymeric reinforcing component;
- e) placing said second polymer into a desired formation;
- f) combining said mixture of step (c) and said formation of step (e) to yield a second mixture; and
- g) subjecting the second mixture of step (f) to heat or pressure.

3. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is in fiber form, with fiber diameter being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component.

4. The composite material according to claim 3 wherein the at least one resorbable polymeric reinforcing component comprises at least one fiber having a variable thickness.
5. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is selected from the group consisting of a fabric, a plain polymeric fiber structure, a woven structure and a braided structure.
6. The composite material according to claim 1 wherein the form of the bioceramic or bioglass reinforcing component is selected from the group consisting of powder, flakes, spheres and fibers.
7. (Cancelled)
8. (Cancelled)
9. The composite material according to claim 1 wherein the amount of bioceramic or bioglass reinforcing component is 0.15 to 0.9 volume fraction.
10. The composite material according to claim 9 wherein the amount of bioceramic or bioglass reinforcing component is 0.2 to 0.6 volume fraction.
11. The composite material according to claim 1 further comprising additives selected from the group consisting of surface modifiers to improve attachment between the resorbable polymeric reinforcing component and the bioceramic or bioglass reinforcing component, a pharmaceutically active agent, and combinations thereof.
12. The composite material according to claim 11 wherein the pharmaceutically active agent is selected from the group consisting of antibiotics, wound-healing agents, chemotherapeutic agents, growth hormones, anticoagulants, and combinations thereof.
13. The composite material according to claim 1 wherein the resorbable polymeric matrix component is selected from the group consisting of polyglycolide, copolymers of glycolide, glycolide/L-lactide copolymers, glycolide/trimethylene carbonate copolymers,

polylactides, stereocopolymers of polylactides, poly-L-lactide, poly-DL-lactide, L-lactide/DL-lactide copolymers, copolymers of polylactides, lactide/tetramethylglycolide copolymers, lactide/trimethylene carbonate copolymers, lactide/d-valerolactone copolymers, lactide/e-caprolactone copolymers, polylactide/polyethylene oxide copolymers, polydepsipeptides, unsymmetrically 3,6-substituted poly-1,4-dioxane-2,5-diones, poly-b-hydroxybutyrate, poly-b-hydroxybutyrate/b-hydroxyvalerate copolymers, poly-b-hydroxypropionate, poly-p-dioxanone, poly-d-valerolactone, poly-e-caprolactone, methylmethacrylate-N-vinyl pyrrolidone copolymers, polyesteramides, polyesters of oxalic acid, polydihydropyrans, polyalkyl-2-cyanocrylates, polyurethanes, polyvinylalcohol, polypeptides, poly-b-malic acid, poly-b-alkanoic acids, polycarbonates, polyorthoesters and polyphosphates.

14. The composite material according to claim 1 wherein the bioceramic or bioglass reinforcing component is selected from the group consisting of hydroxyapatite, calcium phosphates, alumina, zirconia, bioactive gel-glass, alpha wollastonite glass ceramic, and mixtures of bioglass and bioceramic materials.

15. The composite material according to claim 1 wherein the composite material exhibits ductile behavior under load.

16. A biodegradable and bioactive composite material for surgical osteosynthesis applications comprising: i) at least one resorbable polymeric matrix component, ii) at least one resorbable polymeric reinforcing component in fiber form, and iii) at least one bioceramic or bioglass reinforcing component mixed with said matrix component, the diameter of the resorbable polymeric reinforcing component being greater than the diameter or particle size of the bioceramic or bioglass reinforcing component, wherein the bioceramic or bioglass reinforcing component has a particle size between 60 μm and 150 μm .

17. The method according to claim 2 wherein the mixing of step c) is accomplished by melt mixing.

18. The method according to claim 2 wherein the mixing of step c) is accomplished by solvent mixing.
19. The method according to claim 2 wherein step e) is accomplished manually.
20. The method according to claim 2 wherein step e) is accomplished with use of a machine.
21. The composite material according to claim 1 wherein the at least one resorbable polymeric reinforcing component is in fiber form with a fiber diameter between 4 μ m and 800 μ m.
22. The composite material according to claim 21 wherein the fiber diameter is between 20 μ m and 500 μ m.

IX. EVIDENCE APPENDIX

No evidence is being submitted with this Appeal Brief.

X. RELATED PROCEEDINGS APPENDIX

Per section (II), there are no other appeals, interferences, or judicial proceedings known to Appellants, appellant's legal representative, or assignee which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.


XI. CONCLUSION

Appellants respectfully request that the Board of Patent Appeals and Inteferences reverse the Examiner's decision rejecting claims 1-6 and 9-22 and direct the Examiner to pass the case to issue. The Commissioner is hereby authorized to charge the appeal brief fee, the one month extension of time and any additional fees that may be necessary for consideration of this Brief to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON

Date: 1-17-06



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